

FINAL/APPROVED

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF BOARD MEETING**

June 18, 2013  
Second Floor  
Board Room 4

Perimeter Center  
9960 Mayland Drive  
Henrico, Virginia 23233-1463

**CALL TO ORDER:** The meeting was called to order at 9:20AM.

**PRESIDING:** Jody Allen, Vice Chairman

**MEMBERS PRESENT:** Crady R. Adams  
Dinny Li  
Empsy Munden  
Robert M. Rhodes  
Ellen B. Shinaberry  
Pratt P. Stelly  
Rebecca Thornbury  
Cynthia Warriner

**MEMBERS ABSENT:** David Kozera, Chairman

**STAFF PRESENT:** Caroline D. Juran, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
J. Samuel Johnson, Jr., Deputy Executive Director  
Arne Owens, Chief Deputy Director, DHP  
Elaine J. Yeatts, Senior Policy Analyst, DHP  
Heather Hurley, Administrative Assistant  
Charis A. Mitchell, Assistant Attorney General- arrived approximately 1:45pm

**STAFF ABSENT:** Howard M. Casway, Senior Assistant Attorney General

**QUORUM:** With nine members present, a quorum was established.

**APPROVAL OF AGENDA:** Staff presented an amended agenda which included a set of additional minutes from the May 30, 2013 Panel Formal Hearing and the adoption of exempt regulatory action of 18VAC110-20-500 for licensed emergency medical services agencies program. The amended agenda was approved as presented.

**APPROVAL OF MINUTES:** The Board reviewed draft minutes for March 6, 2013 (Telephone Conference Call), March 8, 2013 (Special Conference Committee & Informal Committee), March 12, 2013 (Full Board Meeting), March 12, 2013 (Panel Formal Hearing), March 12, 2013 (Ad Hoc Committee for RFP of Pharmacy Technician Examination), April 9, 2013 (Panel Formal Hearing), April 16, 2013 (Special Conference Committee), April 16, 2013

(Informal Conference Committee), April 17, 2013 (Special Conference Committee), April 17, 2013 (Informal Conference Committee), May 13, 2013 (Ad Hoc Committee on Compounding) and May 30, 2013 (Panel Formal Hearing). A correction was made to page 3 of the March 12, 2013 full board meeting minutes to change "Ellen" to "Shinaberry".

**MOTION:** **The Board voted unanimously to approve the minutes as amended. (motion by Munden, second by Shinaberry)**

**PUBLIC COMMENTS:** There were no public comments offered at this time.

**DHP DIRECTOR'S REPORT:** Arne Owens, Chief Deputy Director for the Department of Health Professions (DHP), presented the Director's report on behalf of Dianne Reynolds-Cane, M.D., Director of DHP. Mr. Owens reported that DHP hosted the National Governors Association (NGA) Prescription Drug Abuse Policy Reduction meeting on March 25, 2013. Virginia is one of five states awarded policy grants to address prescription drug abuse, and DHP is one of several state agencies participating in this public-private effort. The project was broken down into four subcommittees: monitoring; disposal; enforcement; and, training and education. Mr. Owens reported that the committees are discussing possibilities for developing a web-based informational center, improving access to the Prescription Monitoring Program (PMP), encouraging more drug take-back days with improvements made to the coordinating and marketing, and to also encourage a variety of educational and treatment options. Mr. Owens stated that the draft statewide plan is scheduled to be submitted to the Secretary's office by July 1<sup>st</sup>, the Governor's office in August, and the NGA in September.

**LEGISLATION UPDATE:** Ms. Yeatts presented five legislative proposals for the Boards review and approval. The first proposal would conform state law to federal scheduling by placing the new FDA-approved drug, locaserin, into Schedule IV of the Drug Control Act.

**MOTION:** **The Board voted unanimously to approve the legislative proposal to place locaserin into Schedule IV of the Drug Control Act (motion by Adams, second by Stelly)**

The second legislative proposal would reschedule tramadol in the Drug Control Act from a Schedule VI to a Schedule IV. There was discussion that while tramadol is not currently controlled federally under the Controlled Substances Act, twelve states have placed the drug into Schedule IV and another has identified it as a drug of abuse. Ms. Juran reported that the Board has previously approved legislative proposals in past years to place tramadol into Schedule IV, but that the proposals were not included in the Administration packet.

**MOTION:** **The Board voted unanimously to approve the legislative proposal that will reschedule tramadol in the Drug Control Act from a**

**Schedule VI drug to a Schedule IV drug. (motion by Stelly, second by Munden)**

The third proposal would authorize the Board to license the facilities associated with practitioners of the healing arts to sell controlled substances. Ms. Juran indicated that the regulations for this physician dispensing license mirror pharmacy regulations, to include physical and security requirements for the facility, however, the Board does not have authority to license the actual facilities. Because the number of physician dispensing licensees has significantly increased in recent years, it has become increasingly difficult to ensure proper oversight of both the licensed dispensing physicians and the unlicensed drug storage locations or facilities. Ms. Juran confirmed that the proposal would not expand the physician's current authority, but rather formalize an existing process.

**MOTION:**

**The Board voted to approve the legislative proposal that will authorize the Board to license the facilities associated with licensed practitioners of the healing arts to sell controlled substances. (motion by Stelly, second by Adams; Warriner opposed)**

The fourth proposal would authorize health regulatory boards to take additional actions of those summarily restricted or suspended. The Board discussed the draft proposal and suggested that in section C, there needed to be language added "such as a drug recall".

**MOTION:**

**The Board voted unanimously to amend the legislative proposal that will authorize health regulatory boards to take additional actions of those summarily restricted or suspended by adding "including, but not limited to drug recalls" in section C following the word "actions" and approve the proposal as amended. (motion by Adams, second by Stelly)**

Ms. Yeatts provided a handout for the final legislative proposal which would require wholesale distributors and nonresident wholesale distributors to notify the Board and the Virginia State Police within five days of ceasing or restricting distribution of controlled substances to a dispenser due to suspicious ordering. Ms. Juran reported that the description of "suspicious activity" within the proposal is analogous to language in 21CFR 1301.74. Mr. Owens indicated that this proposal was identified during the NGA Policy Grant meetings as an important initiative that could potentially assist in reducing prescription drug abuse.

**MOTION:**

**The Board voted unanimously to approve the legislative proposal that will require wholesale distributors and nonresident wholesale distributors to notify the Board and the Virginia State Police within five days of ceasing or restricting distribution of controlled substances to a dispenser due to suspicious ordering. (motion by**

**Munden, second by Shinaberry)**

**REGULATIONS:**

Ms. Yeatts reviewed the update of the Board's current regulatory actions found on page 70 of the agenda packet. Changes to the run-dry requirement for automated counting devices, amendments to the practitioners of the healing arts to sell controlled substances regulations, and amendments to the regulations governing wholesale distributors, manufacturers and warehouseers are scheduled to become August 2, 2013. Public comment periods for proposed regulations regarding on-hold prescriptions and automated dispensing devices are open until August 2, 2013.

**ADOPTION OF EXEMPT  
REGULATORY ACTION FOR  
LICENSED EMERGENCY  
MEDICAL SERVICES  
AGENCIES PROGRAM,  
18VAC 110-20-500:**

Ms. Yeatts presented a handout to the Board regarding an exempt regulatory action for licensed emergency medical services that stemmed from HB1499. Michael Berg, Manager, Regulation and Compliance for the Virginia Office of Emergency Medical Services, discussed with the Board the positive impact that the amendment would have and answered questions presented to him.

**MOTION:**

**The Board voted unanimously to adopt the exempt regulatory action of 18VAC 110-20-500 for licensed emergency medical services agencies program as presented. (motion by Stelly, second by Rhodes)**

The Board discussed the need for further review of Regulation 18VAC 110-20-500 for licensed emergency medical services agencies to include but not limited to electronic records associated with the process. It was suggested to refer to the matter to the Regulation Committee.

**MOTION:**

**The Board voted unanimously for the Regulation Committee to further review Regulation 18VAC 110-20-500 which shall include but not be limited to electronic records associated with the process. (motion Shinaberry, second by Adams)**

**NABP PRESENTATION  
REGARDING VERIFIED  
PHARMACY PROGRAM:**

Josh Bolin, Government Affairs Director with NABP, provided an overview to the Board of the "Verified Pharmacy Program." This program is currently being developed by NABP and will allow a state board to share information with other state boards for purposes of licensing or disciplinary in regards to pharmacies and non-resident pharmacies, to include those performing compounding. Mr. Bolin stated that NABP has been requested by Iowa and New Jersey to conduct pharmacy inspections on their behalfs. To ensure a uniform inspection process, NABP is surveying all states to develop a uniform inspection report which would include USP 797 and 795 standards. As inspections are completed, the results will be accessible to other states via the Verified Pharmacy Program, unless confidentiality laws in individual states preclude such sharing of information. Mr. Bolin stated that while there is a cost associated with NABP performing inspections, the development of the Verified Pharmacy Program infrastructure to share pharmacy licensing, inspection, and disciplinary information to the states will be provided at no cost to the boards.

Mr. Bolin also reported that of the approximate 500 nonresident pharmacies registered in Virginia; approximately half of those were also licensed by Iowa. Additionally, of the 177 nonresident pharmacies registered in Virginia that indicated they perform sterile compounding, 77 of those are also on Iowa's list.

**ADOPTION OF GUIDANCE  
DOCUMENT 110-38,  
NONRESIDENT  
PHARMACIES TO SUBMIT  
CURRENT INSPECTION  
REPORT:**

Ms. Juran discussed the proposed changes to Guidance Document 110-38 resulting from HB2312 which amends Va. Code §54.1-3434.1 effective July 1, 2013. New nonresident pharmacy applicants must submit an inspection report that was conducted no more than six months prior to the submission of application to the Board. It also states that nonresident pharmacies must submit an inspection report that was performed no more than two years prior to the date of submission of the renewal form. In lieu of the resident state board performing an inspection, which must include a review of USP-NF standards for those compounding, the Board will accept an inspection report from NABP which satisfies the inspection requirements of §54.1-3434.1. Because Joint Commission does not inspect for compliance with USP-NF standards, it was proposed that the Board no longer accept a report from Joint Commission as an acceptable alternative.

**MOTION:**

**The Board voted unanimously to adopt Guidance Document 110-38 as presented and effective July 1, 2013. (motion by Stelly, second by Warriner)**

**ADOPTION OF PROPOSED  
SANCTIONING REFERENCE  
POINTS PHARMACIST  
WORKSHEET:**

Neal Kauder and Kim Small, Research Associates with Visual Research, Inc., reviewed with the Board the revised Sanctioning Reference Points (SRP) Pharmacist Worksheets. The SRP worksheet is designed to assist the board during informal hearing case deliberation in determining appropriate disciplinary action in a consistent manner. Mr. Kauder stated that since 2007, an SRP worksheet was used in 72 pharmacist cases. Because of the increased use of pre-hearing consent orders at the conclusion of routine inspections and annual continuing education audits, the amount of cases involving an SRP worksheet has decreased since 2010. A review of the cases involving an SRP was performed to determine what criteria actually led to disciplinary action being taken. The SRP worksheet was revised based on this review.

The Board discussed concerns regarding the proposed point value assigned to patient harm on the pharmacist worksheet. Ms. Small explained that the category "patient harm" includes cases involving confirmed harm as well as allegations of patient harm with no evidence of harm. It was further explained that egregious cases involving patient harm would likely be referred to a formal hearing and therefore, not subject to the use of the SRP worksheet.

Mr. Kauder also reported that they are in the process of collecting data in order to develop a worksheet for pharmacy technicians. It will be presented to the Board for adoption in September.

**MOTION:**

**The Board voted unanimously to accept the Sanctioning Reference Points Worksheet for Pharmacist as presented. (motion by Thornbury, second by Munden)**

**REPORT ON AD HOC  
COMMITTEE ON  
COMPOUNDING AND  
ADOPTION OF AMENDED  
GUIDANCE DOCUMENT 110-  
36:**

Ms. Allen, Chairman of the ad hoc committee, reviewed the proposed amendments made to Guidance Document 110-36 resulting from the May 13<sup>th</sup> Ad Hoc Committee on Compounding meeting. Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) expressed concerns with the amended guidance document. Mr. Musselman requested that the Board not adopt it at this time, but refer it back to the ad hoc committee for further review and possible adoption by the Board in September. Vicki Garrison, Pharmacy Inspector, stated that she had observed during routine inspections that pharmacists are eagerly awaiting guidance from the Board on compounding issues. Soumi Saha, Kaiser Permanente, stated that there was no mention of whether pharmacists may compound for a physician without having a patient specific prescription and what constitutes manufacturing versus compounding during a possible drug shortage. Ms. Juran explained that the answer to question #33 within the guidance document addressed when a pharmacist may provide a compound to a physician. Additionally, it was stated that the board can amend or add additional FAQs in the future. Ms. Yeatts reminded the Board that it cannot cite a violation of a guidance document, but if the requirement is found in USP then it could cite a violation of USP since the law requires pharmacists performing compounding to comply with USP-NF standards.

**MOTION:**

**The Board voted unanimously to adopt Guidance Document 110-36 as presented. (motion by Stelly, second by Adams)**

**UPDATE ON REVIEW OF  
NONRESIDENT PHARMACY  
COMPOUNDING SURVEYS:**

Ms. Juran gave the Board an update on the review of nonresident pharmacy compounding surveys that were sent December 2012. Staff has continued to review the surveys following the ad hoc committee meeting in February 2013. Ms. Juran also commended Mr. Adams for taking additional time to assist in reviewing the surveys. Ms. Juran requested that the Board authorize staff to issue pre-hearing consent orders to the nonresident pharmacies with monetary penalties based on specific violations that are listed in Guidance Document 110-9.

**MOTION:**

**The Board voted unanimously to authorize staff to issue pre-hearing consent orders with monetary penalties consistent with the suggested monetary penalties found in Guidance Document 110-9 to nonresident pharmacies in violation of law based on the sterile compounding survey responses. (motion by Warriner, second by Munden)**

**REPORTS:**

- **Chairman's Report:**

Ms. Allen reported that Virginia was well-represented at the NABP Annual Meeting held in St. Louis, May 18<sup>th</sup>-21<sup>st</sup>. Attending along with her included Mr. Kozera, Mr. Adams, Mr. Rhodes, Ms. Warriner, Ms.

Thornbury, Ms. Juran and former Board member Leo Ross. The meeting highlights included: presentations on compounding versus manufacturing, NABP's initial approval from ICANN to use the generic Top Level Domain .PHARMACY which would identify legitimate online pharmacies from rogue outlets, the Institute of Medicine's (IOM) recommendation that states require wholesale distributors to obtain NABP's VAWD certification to ensure legitimate distributions within the drug supply chain, and a comparison of biosimilars versus traditional generic drugs. New members of the Executive Committee were inaugurated for the upcoming year, including Karen Ryle who is the new NABP president. Ms. Allen stated that the meeting was very informative and encouraged everyone to attend as many NABP meetings as possible during their tenure as a Board member.

- Report on Board of Health Professions: Mr. Rhodes gave an update regarding previous and upcoming meetings with the Board of Health Professions. It was announced that on July 30, 2013 the Board of Health Professions will hold a public hearing for the pharmacy technician scope of practice review.
- Report on Licensure Program: Mr. Johnson reported that the Board issued 1,022 licenses and registrations for the period of March 1, 2013 through May 31, 2013, including 102 pharmacists, 110 pharmacy interns, and 605 pharmacy technicians. Inspectors conducted 403 facility inspections including 124 routine inspections of pharmacies: 40 resulted in no deficiency, 34 with deficiencies, and 50 with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies and noted the number of Total Major Deficiencies on page one should be 85 rather than 84. Mr. Johnson reported that since January 1, 2013, pharmacy inspectors have identified that 147 of 194 pharmacies inspected were not compliant with the emergency regulations for continuous quality improvement programs. The most frequently occurring area of noncompliance was failure to indicate a zero report when no dispensing errors occurred within the past 30 days.
- Report on Disciplinary Program: Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of June 8, 2012; September 28, 2012; March 8, 2012; and June 14, 2013. For the final date, open cases are none at the entry stage; 50 at the investigation stage; 85 at the probable cause stage; seven at the administrative proceedings division stage; eight at the informal stage; six at the formal stage; and 124 at the pending closure stage.
- Executive Director's Report: Ms. Juran reported that the amendments of law as a result of HB2312 will become effective July 1, 2013. Staff will send out correspondence to all nonresident pharmacies informing them of the new inspection-related requirements and requirement to inform the Board if they intend to begin shipping sterile compounds into Virginia. The Virginia Board of Pharmacy has been selected to host the 2014 NABP/AACP District 1 and 2 meeting October 2014. Ms. Juran stated that she intends to contact the Virginia schools of pharmacy to determine their interest level in

participating in the hosting of the meeting. NABP will assist in the planning process, setting an agenda, obtaining speakers and other details necessary for the meeting. Ms. Juran requested that if anyone had any suggestions on the location to hold the meeting, to please contact her. She will also request recommendations of location from the schools of pharmacy; conduct some preliminary research and work with the Chairman to finalize a decision. Ms. Juran stated that she is currently preparing the budget for the 2015-2016 fiscal years. The Board is in good fiscal condition and is requesting budget approval to hire a P-14 to fill a current vacant administrative assistant position and the addition of one full time employee for a pharmacist position to serve as a supervisor of the licensure program for pharmacists and pharmacy technicians. The hiring requests will require Secretary approval. Ms. Juran also reported the status of the last DEA take-back day that was held April 27<sup>th</sup>. The grand total of drugs collected by Virginia was 22,352.82 pounds.

**RECOGNITION OF BOARD  
MEMBER WHOSE TERM  
EXPIRES ON JUNE 30, 2013:**

Ms. Allen recognized David Kozera in his absence, for serving the past year as Chairman and his continued service over the past eight years to the Board. Mr. Kozera's second full term will expire June 30, 2013. Ms. Allen also thanked former Board member Leo Ross for his thoughtfulness in providing corsages to Board and staff members for Mr. Kozera's end of term.

**INTRODUCTION:**

Ms. Allen introduced Timothy Reilly, Pharmacist, as the new Pharmacy Inspector for the Enforcement Division. Mr. Reilly comes to us with a number of years of experience in pharmacy, DME and home health agency auditing for the Virginia State Medicaid Program. He also has had past experience in retail pharmacy and consulting pharmacy. Mr. Reilly has had REID Investigative training, and previous experience working on fraud cases with the Virginia Attorney General's Office. He will inspect pharmacy-related facilities where needed throughout the state.

**ELECTION OF OFFICERS:**

**MOTION:**

**The Board voted unanimously to elect Ms. Allen as Chairman for the term July 1, 2013 through June 30, 2014. (motion by Shinaberry, second by Warriner)**

**MOTION:**

**The Board voted unanimously to elect Ms. Shinaberry as Vice Chairman for the term July 1, 2013 through June 30, 2014. (motion by Adams, second by Stelly)**

**NEW BUSINESS:**

There was no new business.

**CONSIDERATION OF  
CONSENT ORDERS:**

There were no consent orders for consideration.

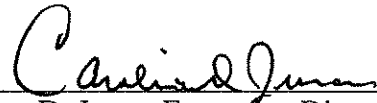
**ADJOURN:**

With all business concluded, the board meeting adjourned at 3:04pm.



  
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Jody Allen, Vice Chairman

Date: 9/10/13

  
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Caroline D. Juran, Executive Director

Date: 9/10/13

DRAFT - WORK IN PROGRESS